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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/762,029	01/20/2004	Jiandong Ding	4614-4000	3917

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EXAMINER

ROGERS, JAMES WILLIAM

ART UNIT PAPER NUMBER

1618

DATE MAILED: 05/03/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/762,029	Applicant(s) DING ET AL.	
	Examiner James W. Rogers	Art Unit 1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 January 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-44 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-44 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|-------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>02/11/2004</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-9, 35,40-44 are rejected under 35 U.S.C. 102(b) as being unpatentable by Pathak et al. (US 6,201,065).

Pathak teaches multiblock biodegradable hydrogels for drug delivery (in aqueous solution) and the method to produce them, the hydrogels can be comprised of PEO-PPO-PEO segment attached to polyesters (polylactide, polyglycolide and polycaprolactone were specifically mentioned) with crosslinkable units (end capped acyloyl chloride is mentioned) the monomeric units are within the ranges specified by applicant; the hydrogels can also be used to deliver a therapeutic protein. See col 5 lin 26-33, col 6 lin 66-col 7 lin 13, col 8 lin 49-63, col 9 lin 18-29, col 10 lin 47-52, col 12 lin 56-63, col 13 lin 43-65 and examples. Regarding the limitation in claim 1 that at least one macromolecule is negative temperature-sensitive is met since Pathak discusses the use of macromolecules which are liquid at RT and gel at body temperature, see col 9 lin 54-55. Regarding claim 7 it is understood that some crosslinked copolymers will comprise unpolymerized ends, the burden is shifted to the applicants to show that the polymers in the Pathak patent would not have the same amount of unpolymerized ends. Regarding claim 8 the Pathak patent discloses microspheres (same as microgel particles) the size of which are within the range listed by applicant. See col 12 lin 18-24.

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Claims 1-7, 9, 35 and 40-44 are rejected under 35 U.S.C. 102(b) as being unpatentable by Hubbell et al. (US 6,306,922).

Hubbell teaches biodegradable aqueous hydrogels as controlled release carriers and the method to make them, the hydrogels are comprised of cross-linked macromers that may consist of a water soluble core of PEO-co-PPO block copolymers and a biodegradable region comprised of various polyesters (polylactide, polyglycolide and polycaprolactone were specifically mentioned), the macromers crosslinked by cross linking agents (end capped acyloyl chloride is mentioned), the hydrogel can carry a therapeutic protein, the above concentrations of the polymer monomers are within the specified ranges listed by the applicant. See abstr, col 7 lin 34-55, col 7 lin 66-col 8 lin 2-3, col 8 lin 8-24, lin 41-49, col 9 lin 15-21, lin 36-62 and examples. The limitation in claim 1 that that at least one macromolecule is negative temperature-sensitive is met since the Hubbell patent discloses the same cross-linked polymer, therefore it's thermo-sensitivity will be the same. Regarding claim 7 it is understood that some crosslinked copolymers will comprise unpolymerized ends, the burden is shifted to the applicants to show that the polymers in the Hubbell patent would not have the same amount of unpolymerized ends.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-44 rejected under 35 U.S.C. 103(a) as being unpatentable over Pathak et al. (US 6,201,065).

The Pathak is disclosed above. Regarding claim 10 part c, 32 and 33 while the Pathak patent does not disclose inverse suspension polymerization but describes an aqueous normal suspension polymerization it would have been obvious to someone skilled in the art at the time of the invention to experiment with different solvents, temperature of the reaction, and stirring speeds and to optimize the parameters for the synthesis of the same cross-linked copolymer. Regarding claim 16 the limitation that the feed molar ratio of F and D is 0.1/99.9 to 99.9/1 is met because Pathak gives several examples and weights of the monomeric materials that would fit in the specified range listed by the applicants. Regarding claim 17-18 stannous octoate (zinc and CaOH were not listed) was used as a ring opening catalyst but the patent is silent on the amount, the temperature and reaction times are within the ranges specified by applicants, it would have been obvious to someone skilled in the art at the time of the

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invention to experiment with different types of catalyst and their amounts. Regarding claims 20-21 the Pathack patent discloses several % wt/wt of macromolecule in water that fall within the ranges specified by applicants. Regarding claims 22-31 a photoinitiator was added but the patent is silent on the amount, the patent also conducted the reaction at temperatures ranging from 0-50 °C, the examiner assumes since the polymers have the same basic structure their gelation temperatures will be the same, besides this it would have been obvious to someone skilled in the art at the time of the invention to experiment with different concentrations of initiator and different temperatures for the reaction. Regarding claim 33 Tween is listed as a surfactant when loading Taxol, the patent is silent on the concentration but it would have been obvious to someone skilled in the art at the time of the invention to experiment with different emulsifier concentrations. Regarding claims 36-39 the entrapment of the substance by controlling the temperature would be obvious to someone skilled in the art at the time of the invention to experiment with different temperatures of the gel in order to change the phase to trap a substance within the gel. Generally, differences in concentration or temperature will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). The normal desire of scientists or artisans to improve upon what is already generally known provides the motivation to determine where in a disclosed set of percentage ranges is the optimum

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combination of percentages."); In re Hoeschele, 406 F.2d 1403, 160 USPQ 809 (CCPA 1969).

Claims 1-32 and 33-44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hubbell et al. (US 6,306,922).

The Hubbell patent is disclose above. Regarding claim 10 part c and 32 and 33 while the Hubbell patent does not disclose inverse suspension polymerization but describes an aqueous normal suspension polymerization it would have been obvious to someone skilled in the art at the time of the invention to experiment with different solvents, temperature of the reaction, and stirring speeds and to optimize the parameters for the synthesis of the same cross-linked copolymer. Regarding claim 16 the limitation that the feed molar ratio of F and D is 0.1/99.9 to 99.9/1 is met because Hubbell gives several examples and weights of the monomeric materials that would fit in the specified range listed by the applicants. Regarding claim 17-18 stanous octoate (zink and CaOH were not listed) was used as a ring opening catalyst within the concentration range listed by applicants the reaction time and temperature are also within the applicants specified range, it would have been obvious to someone skilled in the art at the time of the invention to experiment with different catalyst in order to optimizer the conditions. Regarding claims 20-21 the Hubbell patent discloses several % wt/wt in water that fall within the ranges specified by applicants. Regarding claims 22-31 a photoinitiator (also thermal energy initiators are listed, see col. 9 lin 15-21) was added within the concentration range listed by the applicants, the patent is silent on the temperature of the reaction mixture but it would have been obvious to someone skilled

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in the art at the time of the invention to optimize the reaction temperature. Regarding claims 36-39 the entrapment of the substance by controlling the temperature of the hydrogel would have be obvious to someone skilled in the art at the time of the invention to experiment with different temperatures of the gel in order to change the phase to trap a substance within the gel. Generally, differences in concentration or temperature will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). The normal desire of scientists or artisans to improve upon what is already generally known provides the motivation to determine where in a disclosed set of percentage ranges is the optimum combination of percentages."); In re Hoeschele, 406 F.2d 1403, 160 USPQ 809 (CCPA 1969).

Claims 1-44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hubbell et al. (US 6,306,922) in view of Pathak et al. (US 6,201,065) and in further view of Scranton et al. (US 5,739,210).

The Hubbell patent is disclosed above.

The Hubbell patent is silent on inverse-suspension cross-polymerization, the use of emulsifiers and the temperature of the reaction during cross-polymerization.

The Pathack patent as above discloses the use of Tween as an emulsifier and the temperature of the reaction mixture during cross-polymerization.

The Scranton patent discloses polymers comprising reversible hydrophobic functionalities, which can be used as superabsorbent materials or pharmaceutical coatings. The Scranton patent is used primarily to show that it was well known in the art at the time of the invention to use inverse-suspension cross-polymerization for synthesis of superabsorbent materials (hydrogels). See col 2 lin 38-55.

It would have been obvious to a person of ordinary skill in the art at the time the claimed invention was made to combine the art described in the documents above because Hubbell teaches the same thermosensitive and biodegradable hydrogel to carry an active agent as the applicant and the Pathak and Scranton patent disclose the missing elements of the Hubbell patent namely inverse-suspension cross-polymerization, the use of emulsifiers and the temperature of the reaction during cross-polymerization. The motivation to combine the documents above would be a thermosensitive and biodegradable hydrogel capable of carrying a therapeutic amount of a protein cross-polymerized by inverse-suspension polymerization. Thus, the claimed invention, taken as a whole was *prima facie* obvious over the combined teachings of the prior art.

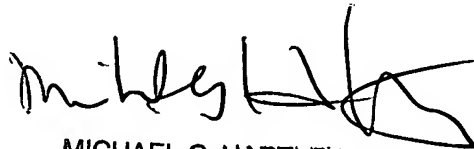
Conclusion

No claims are allowed. Any inquiry concerning this communication or earlier communications from the examiner should be directed to James W. Rogers whose telephone number is (571) 272-7838. The examiner can normally be reached on 8:30-5:00.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



MICHAEL G. HARTLEY
SUPERVISORY PATENT EXAMINER